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10/088,806	09/17/2002	Ammon B Peck	UF141.C4/PCT-US	2652
25871	7590	07/25/2007	EXAMINER	
SWANSON & BRATSCHUN, L.L.C.			KIM, TAEYOON	
8210 SOUTHPARK TERRACE			ART UNIT	PAPER NUMBER
LITTLETON, CO 80120			1651	
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			07/25/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/088,806	PECK ET AL.	
	Examiner Taeyoon Kim	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 10 July 2006.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1,6-8,21-30,33-36,38-42 and 44 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,6-8,21-30,33-36,38-42 and 44 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/31/07.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment/Argument***

Applicant's amendment and response filed on Jul. 10, 2006 has been received and entered into the case.

Claims 1, 6-8, 21-30, 33-36, 38-42 and 44 are pending and have been considered on the merits. All arguments have been fully considered.

The claim rejections under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, to claims 7-8 and 37 are withdrawn due to the amendment.

Applicant's arguments with respect to claims 6-8 have been fully considered and are persuasive. The rejection of claims 6-8 under 35 U.S.C. §102 has been withdrawn.

***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claims 26 and its dependents disclose subject matter of the conditions substantially lethal to differentiated cells. This limitation of the claims does not have any adequate support or description in the specification.

Claim 41 discloses the limitation of "only Idls". There is no antecedent basis for the phrase in the specification.

Claim 44 discloses the phrase "anatomically similar structures" in line 2. There is no antecedent basis for the phrase in the specification.

***Priority***

The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/547,746 (now US 6,001,647), fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The limitation disclosed in claims 6-8, 21-25, 28-30, 42 and 44 (i.e. "about 20 to 25% of the total cells of said Idl are  $\beta$  cells") does not have an adequate support from the application '746. Therefore, the benefit of priority claim, if properly claimed (see below), is granted based on the filing date of application No. 09/406253, which is Sep. 27, 1999.

In addition, Application No. 08/234,071 (now US 5,834,308), fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The limitation disclosed in claims 1, 26, 27, 33-36 and 38-41 does not have an adequate support from the application '071 (i.e. "glucose less than about 1 mM", "epithelial monolayer", "encapsulated", etc.). Therefore, the benefit of priority claim, if properly claimed (see below), is granted based on the filing date of application No. 08/547746, which is Oct. 25, 1995.

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. §120, a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35

U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33, 34, 38, 39 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Since claim 33 only discloses a step of culturing the

IPSC and ductal epithelium composition, it is not clear how to analyze the differentiation of pancreatic stem cells as in the intended use of the method. It appears that the step disclosed in claim 35 would be a proper and critical step omitted in the instant claim.

Claims 1, 24, 33, 41 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 discloses a step (b) of initiating differentiation. The method and means for differentiating IPSCs into IPCs and Idls are critical to the claimed invention and thus must be recited in the claims. It appears that the specification (see p.8) discloses a means for differentiating IPSCs.

Claim 24 discloses the term IPSCs further limiting claim 21. Since claim 21 depends on either claim 6 or 7, and claim 6 does not disclose IPSCs, there is no sufficient antecedent basis for the term "IPSCs".

Claim 33 recites the limitation "the IPSC and ductal epithelium composition" in line 2. There is insufficient antecedent basis for the term "composition" in the claim.

The claim rejection to claims 38 and 39 stands rejected because although the specification discloses the term, the claims exclude essential steps and it is unclear what is necessary to carry out the claimed invention. It is not clear whether "serial transfer" is meant to be "serial passage", which requires steps of detaching cells, harvesting, dissociating and re-plating to a new culture plate/flask, and is a routine laboratory technique to propagate cells in culture, or clear whether it requires no more than simple transfer of cells from one culture substrate to another in a serial manner

without any further treatment to the cells. Further, the method appears to require more than simply carrying out serial transfer of cells/tissues. It would also require specific culture condition.

In addition, even though the term is well known in the art, it is still not clear what kind of procedure the “serial transfer” would be. This is because “serial transfer” does not confine to cell culture procedure rather it is also applied in gene transfer procedure as evidenced by Athwal et al.

Claim 41 discloses the limitation of “only Idls”. It is not clear whether the limitation intends to point out Idls without containing any IPSCs or IPCs, or it is without any other additional constituents for implantation such as growth factors, additives, etc.

Claim 44 discloses a limitation “anatomically similar structures”. It is not clear what subject matter this limitation intends to point out. It is not disclosed which organ structures the limitation points out.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 26-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for pancreatic cells comprising IPSCs, does not reasonably provide enablement for any pancreatic cells without IPSCs. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The current invention is drawn to a method to growing IPSCs, IPCs and

Idls, and treating pancreatic disease using ANY pancreatic cells from a mammalian species. It is well supported by the specification that a population of pancreatic cells comprising IPSCs initially would grow into pancreas-like structure or Idls under the specific culture conditions disclosed in the specification. However, since it is required to have IPSCs initially in the starting cell population, those cell populations which do not contain any IPSCs, for example, isolated population of  $\alpha$  or  $\beta$  cells from pancreas would not possess an ability of pluripotency or contain pluripotent stem cells to differentiate into islets, would not have such property to differentiate into Idls or pancreas-like structure even under the culture condition given in the instant application. For example, various different pancreatic tumor cell lines are not known whether these cells be able to differentiate into Idls. Furthermore, even if a person of ordinary skill in the art would have used a normal pancreatic cells from a mammalian source, considering the low percentage of IPSCs present in the whole pancreatic tissue, unless the starting cell population clearly has IPSCs, a person of ordinary skill in the art would not have been enabled to use the method to grow Idls and treat a pancreatic disease.

Claim 42 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment made to the claims now introduces a new matter situation. The new limitation of "consisting essentially of" changes the scope of the claim.

M.P.E.P. § 2111.03 clearly indicates that the transitional phrase “consisting essentially of” limits the scope of a claim to the specified materials or steps “and those that do not materially affect the basic and novel characteristic(s)” of the claimed invention. *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original). “A ‘consisting essentially of’ claim occupies a middle ground between closed claims that are written in a ‘consisting of’ format and fully open claims that are drafted in a ‘comprising’ format.” *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998), *et al.* For the purposes of searching for and applying prior art under 35 U.S.C. §§ 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964) *et al.* Since the specification in this case does not particularly point out the basic and novel characteristics of the claimed composition, “consisting essentially of” in claim 42 has been interpreted as “comprising” for the purpose of art rejections.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public

use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-8, 21, 25, 26, 33-36, 40-42 and 44 are rejected under 35 U.S.C. 102(b) as being anticipated by Archer et al. (US 4,439,521) in light of Gmyr et al. (1997, IDS reference).

Claims 6-8, 21, 25, 26, 33-36, 40-42 and 44 are drawn to an in vitro produced Idl using the method of growing; a method of treating pancreatic disease such as insulin-dependent diabetes by implanting Idls secreting hormones to an autologous subject; a method of analyzing differentiation of pancreatic stem cells by culturing IPCs and ductal epithelium, differentiating and identifying the stage using mRNA or protein markers; a method for inducing neovascularization in a pancreatic implant comprising transplanting the pancreatic implant comprising Idls into the mammal; a pancreas-like structure produced by implantation, comprising at least 50% by weight of endocrine tissue; a limitation to the structure comprising endocrine cells arranged in Idls.

Archer et al. teach a pancreatic islet-like structure differentiated in vitro from pancreatic ductal pieces, cell clusters consisting of mildly digested pieces of pancreas (pancreatic cells) from human or animal pancreas (column 4, line 18-19) (see Abstract; column 4, line 35-38). The pancreatic islet-like structure is able to secrete hormones such as insulin/proinsulin (see Abstract). It is well known in the art that pancreatic ductal pieces would inherently contain IPSCs and IPCs as evidenced by Gmyr et al. Gmyr et al. teach that human ductal pancreatic stem cells can be obtained from pancreatic ductal tissue. Since the source of cells used in the reference, ductal epithelial cells, is pancreatic cells and these cells are clearly able to differentiate into pancreatic islet

tissue over long-term culture, the examiner takes the position that the islet formed by the method and the source of Archer et al. would be the same as the IdI disclosed in the instant invention.

Note that MPEP § 706.3(e) states that: "[w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 35 U.S.C. 102 or 35 U.S.C. 103 of the statute is appropriate. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. A lesser burden of proof is required to make out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional fashion. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972); *In re Fessmann*, 180 USPQ 324 (CCPA1974)." See, *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) ("the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product"). As there is no clear difference between the claimed products and the prior art products, the rejection under 35 USC 102 is proper.

MPEP § 2112 explicitly states that: The PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on "inherency" under 35 U.S.C. 102, on "prima facie obviousness" under 35 U.S.C. 103, jointly or alternatively,

the burden of proof is the same... [footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. Quoting *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (itself quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 - 34 (CCPA 1977)).

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not Applicants' claims differ and, if so, to what extent, from that discussed in the references. Therefore, with the showing of the references, the burden of establishing novelty by objective evidence is shifted to Applicants.

Archer et al. teach analysis of proinsulin-insulin biosynthesis after culturing and differentiating pancreatic stem/progenitor cells including ductal epithelial cells (see columns 10-11).

Archer et al. also disclose a method of treating pancreatic disease by implanting the pancreatic islet-like structure (ILS) (see column 1, lines 46-49). Since the method of implanting pancreatic islet-like structure is carried out according to Archer et al., the method would inherently induce neovascularization as a result of the implantation of the islet structure.

Since the pancreatic islet-like structure of Archer et al. would be comprised mostly of  $\alpha$  and  $\beta$  cells, which are endocrine cells secreting hormones, the examiner takes the position that the islet-like structure of Archer et al. would be comprising at least 50% by weight of endocrine cells. The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicants' islet-like structure differs, and if so to what extent, from the pancreas islet-like structure

discussed in Archer et al. Accordingly, it has been established that the prior art islet-like structure demonstrates a reasonable probability that it is either identical or sufficiently similar to the claimed islet-like structure that whatever differences exist are not patentably significant. Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants. Merely because a characteristic of a known islet-like structure is not disclosed in a reference does not make the known islet-like structure patentable. The new islet-like structure possesses inherent characteristics which might not be displayed in the tests used the reference. Clear evidence that the islet-like structure of the cited prior art do not possess a critical characteristic that is possessed by the claimed islet-like structure, would advance prosecution and might permit allowance of claims to applicants' islet-like structure.

Thus, the reference anticipates the claimed subject matter.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Archer et al. (supra).

Claim 24 is drawn to limitations to the method of treating pancreatic disease or producing a pancreas-like structure by implanting the Idls wherein the IPSCs being originated from the same mammal.

Archer et al. anticipate claim 21 and therefore, renders the claim obvious (see above).

Although Archer et al. do not teach the source of IPSCs being the same mammal wherein the IPC-derived islets (Idls) is implanted (homologous implantation). It would have been obvious for a person of ordinary skill in the art to use autologous/homologous subject for transplantation/implantation of in vitro grown islets, because by using autologous tissues such as pancreas-like structure or Idls in transplantation/implantation would be beneficial to decrease host's immune response, and the person of ordinary skill in the art would have had a reasonable expectation of success in using tissues from the same subject for transplantation/implantation.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Claims 22, 23 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Archer et al. (supra) in view of Skjak-Braek et al. (WO/1991/09119;

IDS reference).

Claims 22, 23 and 27 are drawn to the Idls being encapsulated in a capsule permeable for insulin, glucagon and somatostatin, prior to implantation, and the capsule being hyaluronic acid.

Archer et al. do not teach the use of encapsulation step of the islets formed from pancreatic cells.

Skjak-Braek et al. teach micro-encapsulation of insulin-producing cells for implantation and transplantation, which provides enhancement of the release of proteins and protection against immunoglobulins (see Abstract).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to encapsulate the islet-like structure of Archer et al.

The skilled artisan would have been motivated to make such a modification because encapsulation would provide protection and enhancement of protein release (hormone release) in islet-like structures upon implantation according to Skjak-Braek et al.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

Claims 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Archer et al. (*supra*) in view of Juang et al. (1996).

Claims 28-30 are drawn to the implantation of islets formed from IPCs at the mammal's pancreatic tissue, a subcutaneous pocket of the mammal, or at beneath a kidney capsule in the mammal.

Archer et al. do not teach the different sites of implantation.

Juang et al. teach various different sites of islet transplantation including kidney capsule, subcutaneous sites and pancreas itself (see p.2, lines 1-3).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the site of implantation taught by Juang et al. in the method of Archer et al.

The skilled artisan would have been motivated to make such a modification because implantation of islets disclosed in Archer et al. can be carried out those sites listed in the reference of Juang et al. because those transplantation sites are well known in the art and commonly used for transplantation/implantation of islets as taught by Juang et al., and therefore, the person of ordinary skill in the art would have had a reasonable expectation of success.

Therefore, the invention as a whole would have been *prima facie* obvious to a person of ordinary skill at the time the invention was made.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d)

may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 1 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 5, 8, 11 and 19 of U.S. Patent No. 6,001,647. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims disclose a method for producing pancreas islet-like structure by culturing pancreatic cells under the condition identical each other (i.e. 0.5% or less serum and below about 1 mM of glucose, undisturbed at least 3 weeks). Therefore, the claims of '647 anticipate the claim of the current application, and therefore render the claim 1 obvious.

### ***Conclusion***

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is 571-272-9041. The examiner can normally be reached on 8:00 am - 4:30 pm ET (Mon-Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

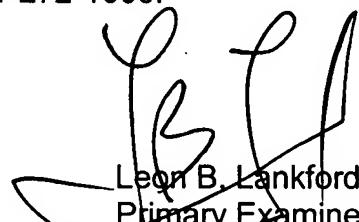
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Leon B. Lankford, Jr.  
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